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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,659	11/12/2003	Joseph L. Witztum	034123-014	3280

41790 7590 01/12/2006

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EXAMINER	
COOK, LISA V	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,659	WITZTUM ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-32* is/are rejected.

7)☒ Claim(s) *29-32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/12/03 & 3/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. Applicants' preliminary amendment filed 11/12/03 is acknowledged. Claims 1-26 have been cancelled. New claims 27-32 are pending and under consideration.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered. See pages 19 and 20.

3. The Information Disclosure Statements filed 11/12/03 and filed 3/29/04 were considered as to the merits prior to first Acton.

Oath/Declaration

4. A new oath or declaration is required because:

> A. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Please see the entry for ZIP for inventor Witztum. Dual date entry for inventor Palinski. Mailing address corrections for Palinski. (Please see the oath filed 11/12/03)

The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

5. The disclosure is objected to because of the following informalities: the first line of the disclosure should be updated to include US Patent Application Number 09/699,131 now US Patent #6,716,410. Appropriate correction is required.

Claim Objections

6. Claims 30 and 32 are objected to because of the following informalities: Claims 30 and 32 are dependent on cancelled claims. Specifically, claim 30 is dependent on cancelled claim 3 but appears to be intended to depend from claim 29. Claim 32 is dependent on cancelled claim 5 but appears to be dependent from claim 31. Appropriate correction is required.

7. Claim 29 is objected to because of the following informalities: A typo appears in the claim "*in vivo*at" should be "*in vivo* at". Appropriate correction is required.

8. Claim 31 is objected to because of the following informalities: The claim does not include the appropriate reference for sequence identification numbers. The claim should be re-written to refer to the sequences as SEQ ID NO:1 and SEQ ID NO:2. Please correct accordingly.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 29 is vague and indefinite because it is not clear as to what the antibody will be "specific for" or "bind to".

As recited it is not clear if the antibody binds either atherosclerotic plaques, OxLDL, or MDA-LDL? Or will the antibody bind all three atherosclerotic plaques, OxLDL, and MDA-LDL? As recited the metes and bounds of the claim cannot be determined.

B. Claim 31 is vague and indefinite because it recited an antibody comprising a variable light chain of encoded by a nucleotide sequence of SEQ ID 1. The wording "of encoded" is not clear. Does applicant intend to recite an additional composition or only SEQ ID 1. It is suggested the term "of" be removed for clarity.

C. The term "fragment thereof, fragment antibody, and single chain fragment" in claims 28, 30, and 32 are relative terms, which renders the claim indefinite. The term "fragment" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what if any fragments would maintain the activity of the antibody or sequence set forth in claims. Accordingly the claim is not clear.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

10. Claims 27-32 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

11. Claims 27-32, as written, do not sufficiently distinguish over serum as it exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Human antibodies are products of nature.

In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page 4 lines 3-20 of specification, for example. See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabled for the claimed antibodies because the instant specification is not in compliance with the biological deposit rules. Claims 27-32 are directed to antibodies having particular binding specificity (like IK17, comprising SEQ ID NO:1/SEQ ID NO:2, binding atherosclerotic plaques, binding OxLDL, or binding MDA-LDL). However, the claimed antibodies have not been deposited under the provisions of the Budapest treaty. Furthermore, filling of an affidavit or declaration by Applicant or assignee or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this

Application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required.

Without such a statement, it would be impossible for the skilled artisan to practice the invention of claims 27-32 because other clones made from the source material have no predictable reasonable expectation of success of being identical to the instantly claimed antibodies.

In the absence of any guidance other than to the use of the Mab IK17, one would not know or be able to predict what structure or modifications were important and the amount of experimentation required to determine same would be undue. Note that an enabling disclosure for the preparation and use of only a few analogs of a product does not enable all possible analogs where the characteristics of the analogs are unpredictable.

Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful antibodies as recited in the instant invention without the prior demonstration of specific limitations that have not been recited. Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (18 USPQ 2d 1027 (CAFC 1991)).

13. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In particular, claim 27 is drawn to any antibody having the binding specificity of the IK17 antibody, claim 29 is drawn to an antibody recognizing the following sites (i) the antibody is specific for oxidation specific epitopes present in the core of atherosclerotic plaques; and (ii) the antibody is specific for oxidized low density lipoprotein and malondialdehyde low density lipoprotein.

Further, it is not known how the monoclonal antibody having single binding specificity will bind both oxidized low-density lipoprotein and malondialdehyde low-density lipoprotein simultaneously. The claims and specification fail to provide the identity or structure of this antibody recognition site.

The specification does not provide evidence of a nucleic acid sequence, other than the sequence of SEQ ID NO: 1 and SEQ ID NO: 2 which are known in the art. From these known sequences primers are produced with the claimed inventive properties; however the specification does not state the identity to a deposited antibody, amino acid sequence, nucleic acid sequence, or any structural characteristics of any other antibody, amino acid sequence, or nucleic acid sequence that has the claimed characteristics.

Moreover, there is evidence that other sequences have not yet been identified therefore; applicants' vague description of an isolated nucleic acid sequence (primers from SEQ ID NO: 1 and SEQ ID NO: 2) has not been adequately described. In view of the lack of evidence, it is apparent that Applicants were not in possession of the unlimited number of primers which may be produced from the known sequences of SEQ ID NO: 1 and SEQ ID NO: 2, at the time of filing the instant application.

The skilled artisan cannot envision the detailed structure of the infinite possible antibodies, amino acid sequences, or isolated nucleic acid sequences, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The nucleic acid structure is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

The antibody activity characteristics and tail domain requirements distinguish the antibody only by what it does, i.e., protein activity, which are purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims describe an isolated monoclonal antibody by its protein function, however this description does not describe the claimed antibody itself. See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement which defines a genus of a compound/seq.id/etc. by only their functional activity does not provide an adequate written description of the genus.
The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description ...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus a skilled artisan cannot envision all the contemplated recognition sequence sites by the detailed chemical structure of the claimed antibody, therefore conception cannot be achieved until reduction to practice has occurred. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant does not provide guidance for the above noted monoclonal antibodies and provides no guidance as to what modifications or structure are important for the predictable function of the monospecific antibody. Very different structures may be found on antibodies with the same specificity. For example, very different V_H chains can combine with the same V_L chain to produce antibody binding sites with nearly the same size, shape, antigen specificity, and affinity.

A similar phenomenon can also occur when different V_H sequences combine with different V_L sequences to produce antibodies with very similar properties.

These observations indicate that divergent variable region sequences, both in and out of complementarily determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. Conversely, similar structure may be found on antibodies having different specificities.

14. Claims 28, 30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO:1 and SEQ ID NO:2 and therefore the written description is not commensurate in scope with the claims drawn to fragments thereof, fragment antibody, and single chain fragment. However no such fragments have been shown in the specification nor exemplified in the method as claimed. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:1 and SEQ ID NO:2, the skilled artisan cannot envision the detailed structure of the encompassed fragments and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polynucleotide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of SEQ ID NO: 1and SEQ ID NO:2 is made in the specification. This is insufficient to support the claims drawn to the fragments thereof as provided by the Interim Written Description Guildlines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated antibody sequences consisting of SEQ ID NO:1 and SEQ ID NO;2 , but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Double Patenting

15. Double patenting obviousness-type rejection:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 27-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-12 of US Patent No. 6,375,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are drawn to antibodies that bind OxLDL (oxidized LDL). See instant specification page 6 regarding IK17 binding to both OxLDL and MDA-LDL.

US Patent #6,375,925differs from the instant invention is using monoclonal antibodies MDA2 and NA59. However the instant claims are drawn to any detectably labeled human or humanized Mab or fragment thereof, Fab, or scFv with specific epitopes present in the core of atherosclerotic plaques. Thus it would have been obvious to one of ordinary skill in the art that the instant invention is encompassed within the claims of US Patent #6,375,925.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

I. Claims 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Witztum et al. (US Patent #6,225,070)

Witztum et al. disclose monoclonal antibodies that specifically bind oxidation-specific epitopes on lipoprotein in blood, arterial tissue and vascular tissue, including atherosclerotic plaque formed in arterial tissue and vascular tissue. See abstract.

Several monoclonal antibodies are disclosed (See tables I and II). E06, E013, E014, and E017 were shown to bind MDA-LDL and oxLDL (Cu 2+ oxidized LDL) – meeting the antibody requirement found on page 4, lines 22-24 of the instant disclosure. The labeled antibodies were employed to image in vivo atherosclerotic plaque (column 10, section B). Various detection procedures are given in column 10, lines 37-53. (therein meeting the limitations of claims 8 and 9). The antibodies are delivery dosage to the host ranges and is dependent on the desired effect (column 14, lines 18-31).

II. Claims 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Sotiriadou et al. (International Journal of Biological Markers, 1996, Vol.11., No.4, pages 183-189) Abstract Only.

Sotiriadou et al. disclose the antibody IK17 and therefore discloses the instantly claimed antibodies binding with the same specificity to Ox-LDL and MDA-LDL and further comprising SEQ ID NO:1 and SEQ ID NO:2.

18. For reasons aforementioned, no claims are allowed.

Remarks

19. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Selley et al. (WO 94/23302) teach an immunological ELISA assay employing antibodies to measure oxidatively modified human low density lipoproteins in plasma samples.

B. Holvoet et al. (Journal of Clinical Investigation, Vol.95., No.6., 1 June 1995, pages 2611-2619) disclose a method for detecting MDA-modified LDL. A monoclonal antibody (mAb-1H11) which to bind with MDA-modified LDL ($ka=10^9\ M^{-1}$) and to a much lesser extent with OxLDL (page 2613, column 2, paragraph 1) is described in an immunoassay format.

20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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